

REMARKS

Claims 1-20 are pending in the instant application. While claims 15-17 have been objected to as containing allowable subject matter, claims 1-14 and 18-20 stand rejected on prior art grounds.

At the outset, Applicants wish to thank Examiners Mendoza and Dawson for taking the time to discuss this application with Applicants and their representative. Accordingly, the amendments and remarks herein are in response to the Office Action of November 4, 2004 and commensurate with the agreements of the personal interview of January 27, 2005. In particular, with regards to device claims 1-17, Applicants have amended claim 1 to include the limitations of claim 8, now canceled. To ensure proper dependency, claim 9, previously dependent upon claim 8, has been amended to depend directly from claim 1. As amended, claim 1 now specifies that the resistive heating element is affixed at its proximal end to the distal end of the second conductive member and at its distal end to the tapered tip at the distal end of the first conductive member. Support for this amendment is found in the specification as originally filed, particularly p. 6, lines 24-27, original claim 8, and Figure 3. Applicants respectfully submit that the presently claimed configuration is distinct from that of Warthen, which expressly requires the presence of a V-shaped notch disposed between the first and second conductive members for receiving and severing the tails of suture knots. With regards to pending method claims 18-20, which stand rejected for being obvious, while Applicants strongly submit that the rejection is in error, to expedite prosecution, Applicants submit herewith the Rule 132 declaration of Dr. Steven Remsen to serve as the evidence of non-obviousness requested by Examiner Dawson.

Accordingly, Applicants submit that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicants submit the following remarks:

Rejections under Section 102:

Claims 1-3, 5-12, and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Warthen, U.S. Patent No. 4,845,851. According to the Examiner, Warthen teaches a suture removal instrument that anticipates Applicants' claims. Applicants respectfully disagree. In order to anticipate a claim, a single reference must disclose each and every element of the claim. In this case, contrary to the Examiner's suggestion, Warthen does not teach a "suture removal device". In fact, the Warthen device is neither used for, nor is it capable of, removing sutures. Rather, the Warthen device is specifically adapted for "heat cutting [suture] knot tails" so as to provide "significantly improved knot security for sutures comprised of synthetic materials." Col. 1: 23-26. To that end, the Warthen device comprises a cutter head for separating suture tails, including a heating element that "forms all or part of a notch, a generally V-shaped portion of the cutter head, that allows a wide variety of suture diameters to slide through it while the operator slides the cutter head down along the suture tails until the device comes into engagement with the knot." Col. 2: 2-9. This notch is noticeably absent from Applicants' invention. To clarify this configuration and expedite prosecution, claim 1 now specifies that the resistive heating element (15) is affixed at its proximal end (16) to the distal end (13) of said second conductive member (8) and at its distal end (17) to the tapered tip (11) of said first conductive member (7). See, for example, Applicants' Figure 3. Conversely, for the Warthen device to function as specified, the resistive heating element (20) must be affixed at a point on the second conductive member (12) that is sufficiently proximal to the distal end of said second conductive member, i.e., the second conductive member must extend beyond the resistive heating element to form one side of the V-shaped notch. See, for example, Warthen Figures 1, 5, 6, and 8. As the Warthen reference fails to disclose the claimed arrangement, it cannot anticipate the invention as presently claimed.

Applicants respectfully submit that Warthen fails to disclose other claim limitations.

For example, Applicants respectfully submit that Warthen does not disclose or suggest a first conductive member that terminates in a "tapered tip" (claim 1, part (c)). The generally accepted definition of the adjective "tapered" is "gradually decreasing in size toward a point". See, for example, the American Heritage® Dictionary of the English Language, Fourth Edition, 2000. This plain meaning is reflected in Applicants' figures, particularly Figure 3 which depicts the distal end of the first conductive member as narrowing gradually to a sharp point (i.e.,

terminating in a “tapered tip”). Conversely, while the flat conductive strip of Warthen may indeed be described as beveled or angled, it does not comprise a “tapered tip” as recited in claim 1. Accordingly, as Warthen fails to disclose a tapered tip, it cannot anticipate the claimed invention.

With respect to claim 5, it appears that the Examiner may have overlooked a portion of the claim. While Warthen’s conductive strip (element 14) may indeed be flat, it does not comprise a flat “scoop”, given the definition of this term set forth in the specification and the plain meaning of the term. For example, at page 3, lines 20-21, Applicants define the “scoop” as shovel or spade-shaped. Likewise, in the medical context, a “scoop” is a narrow, spoon-like instrument, often used for surgical extraction in cavities or cysts. See Merriam-Webster Medical Dictionary, © 2002 Merriam-Webster, Inc. As noted in the specification, the scoop shape facilitates insertion of the tapered tip into a suture loop, allowing it to gently slide under the loop of the suture. Accordingly, claim 5 does not merely require the tapered tip of the first conductive member to be flat but to also be a spoon or shovel shaped scoop. As the Warthen reference fails to disclose or suggest the inclusion of a flat scoop at the distal end of the first conductive member, it cannot anticipate the invention of claim 5. Moreover, there is no suggestion in the Warthen reference to shape his conductive member thusly. Such a modification would not only be unnecessary but also would run counter to the intended purpose of the element, whose sole purpose is to direct the suture material into the notch of the cutting head. Accordingly, the Warthen reference neither anticipates nor renders obvious the invention of claim 5.

In sum, as the Warthen reference fails to disclose one or more claim elements of the pending claims, it cannot anticipate the invention as presently claimed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-3, 5-12, and 14 under 35 U.S.C. § 102(b) as being anticipated by Warthen.

Rejections under Section 103:

Claims 4 and 13 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Warthen. According to the Examiner, while Warthen fails to teach a tapered tip with a conical point as recited in claim 4, it would have been obvious to modify it to include such "because the shape of the tapered tip is a mere design choice and that any shape would perform equally well." With respect to claim 13, the Examiner suggests that it would have been obvious to modify the Warthen device to include a power cord adapted for connection to a wall outlet as recited in claim 13 so as to "supply the suture removal instrument with a constant supply of power as opposed to a battery that can be exhausted."

Applicants respectfully disagree. To establish a *prima facie* case of obviousness, there must be some teaching, suggestion, or motivation to make a proposed modification, either explicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. At the very least, the prior art must suggest the desirability of the proposed modification. In this case, with respect to claim 4, Applicants respectfully submit that there is no motivation, either in the reference or in the prior art, to provide the distal end of Warthen's conductive member with a tapered, conical point. A conical point is particularly useful when a device must penetrate a confined space. For example, in the instant invention, the tapered conical point facilitates the painless insertion of the conductive member between the patient's skin and the suture loop. The Warthen device is not used in this manner and, thus, there is no incentive to modify the conductive member of his device as suggested, particularly given the fact that a conical point is much more difficult and costly to manufacture than a flat plate.

As there is no suggestion in the art to make the proposed modification, the invention is not rendered *prima facie* obvious by the Warthen reference. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4 and 13 as obvious in view of Warthen.

Claims 18-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over Tischlinger, U.S. Patent No. 4,384,406, in view of Warthen. According to the Examiner, Tischlinger teaches a method for removing sutures from the skin of a patient but fails to teach applying heat to a loop of the suture so as to cut the suture loop. Accordingly, the Examiner cites to Warthen to cure this deficiency. The Examiner concludes that it would have been obvious to one of ordinary skill in

the art to "use the device of Warthen to apply heat to cut a suture loop as an alternative suture cutting means."

Applicants respectfully disagree. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the cited prior art and not based on Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also M.P.E.P. § 2143. The instant rejection fails on all three counts for the following reasons:

First of all, there is no suggestion, either in the references themselves or the prior art in general, to use the Warthen device as a "suture cutting means" as proposed by the Examiner. As discussed above, the Warthen device is not used to cut suture loops; rather, the Warthen device is used to sever the tails of a suture knot (i.e., the excess amount of suture not involved in formed in the suture loop) so as to yield a slip resistant, secure knot. See Abstract, lines 1-2; col. 1: 4-5, 11-13). As noted above, the Warthen device is specifically configured for this purpose, including a generally V-shaped heating element "that allows a wide variety of suture diameters to slide through it while the operator slides the cutter head down along the suture tails until the device comes into engagement with the knot." Col. 2: 3-9. As the entire purpose of the Warthen device is to strengthen and improve internal sutures which are intended to remain in the body, use thereof to remove sutures is clearly not suggested. Thus, as the Warthen reference teaches away from the claimed purpose, the Warthen reference, alone or in combination, cannot be used to establish a *prima facie* case of obviousness.

Second, it is readily apparent that the Warthen device is neither suited for the claimed purpose nor able to perform the claimed function. Specifically, the notched cutter head of the Warthen device is unsuitable for sliding under a suture loop disposed on the skin of a patient. Furthermore, even if one were able to do so, it would be extremely difficult to position the heating element so as to heat and cut the suture loop without simultaneously injuring the patient. Finally, Warthen teaches that "the portion of the knot tails remaining after severance are

generally somewhat swollen making it more difficult for them to pass back through the knot itself thereby preventing the knot from slipping.” (col. 2: 21-24). Accordingly, even if one tried to use the Warthen device for the clearly unintended purpose of cutting suture loops, he would be unsuccessful as the swollen severed ends would lock the remaining suture thread in place, thereby preventing rather than facilitating removal. Accordingly, as there is no reasonable expectation that the Warthen device could successfully perform the recited function, the Warthen reference, alone or in combination, cannot be used to establish a *prima facie* case of obviousness.

Finally, with respect to claim 20, it is important to note that neither Warthen nor Tischlinger, alone or in combination, suggest a suture removal instrument as recited in claim 1, including a resistive heating element extending between the tapered tip of a first conductive member and the distal end of a second conductive member. As the cited references fail to teach or suggest all the claim limitations, the combination is insufficient to render the pending claims *prima facie* obvious.

During the personal interview of January 27th, Examiner Dawson argued that one would have been motivated to utilize the Warthen device to remove sutures from the skin of a patient, noting that almost any device could be used to perform the steps recited in claims 18 and 19. However, the Examiner is reminded that “capable of”, like “obvious to try”, is an inappropriate standard for determining anticipation or obviousness of a claimed process. “That which is within the capabilities of one skilled in the art is not synonymous with obviousness.” *Ex parte Levengood*, 28 USPQ 2d 1300 (BPAI, 1993) at 1301-1302. In other words, the fact that one of ordinary skill in the art has the capability of arriving at the claimed invention is not the test for whether one of ordinary skill would have arrived at the invention based on the teachings of the prior art. Rather, it is the Examiner’s burden to provide a convincing line of reasoning as to why the artisan would have found the claimed invention to be obvious in light of the teachings of the references. See *Ex part Clapp*, 227 USPQ 972, 973 (BPAI, 1985), as well as M.P.E.P. § 2144 – “§ 2144.09. Furthermore, while functional language related to “intended use” is often deemed non-limiting when evaluating a device claim, such is the crux of a process claim and cannot be summarily dismissed in determining obviousness. As the Supreme Court stated in *Carnegie Steel Co. v. Cambria Iron Co.*, “a process...is not anticipated [or rendered obvious] by a [prior art] mechanism which *might*, with slight alterations, have been adapted to carry out the process

unless, at least, such use of it would have occurred to one whose duty it was to take practical use of the device described.” *Carnegie Steel Co. v. Cambria Iron Co.*, 185 U.S. 403 (1902) at 424 (emphasis added). In other words, while “a mechanical patent is anticipated by a prior art device of like construction and capable of performing the same function. . . a process claim can only be anticipated [or rendered obvious] by a similar process.” *Id* at 424. Accordingly, the mere fact that one *might* have been able to use the Warthen knot tail cutter to remove a suture from the skin of a patient is irrelevant to a finding of obviousness. As noted above, since the Warthen reference is devoid of any suggestion of “applying heat to the loop of a suture so as to heat and cut the suture loop” as recited in claim 18, more particularly “inserting a resistive heating element under the loop of a suture” as recited in claim 19, and in fact teaches away from the claimed purpose, the Warthen reference, alone or in combination, cannot be used to establish a *prima facie* case of obviousness. Further to this position, Applicants submit herewith the Rule 132 declaration of Dr. Steven Remsen, a medical professional skilled in the art of suture removal. As stated in the declaration, in view of the risks involved and the substantial doubt concerning “success”, Dr. Remsen would not have been motivated to utilize the Warthen device as proposed by the Examiner. As such, the Examiner’s suggestion that one skilled in the art would have been motivated to utilize the Warthen device to perform the methods of claims of 18 and 19 is unfounded and not commensurate with the teachings of the art and the opinions of those skilled in the art.

In sum, Applicants respectfully submit that not only is there no motivation to combine the references as suggested, but even if the references were combined as suggested, one would not arrive at the invention of the pending claims. Accordingly, Applicants request reconsideration and withdrawal of the rejection of method claims 18-20 as being obvious over Tischlinger in view of Warthen.

Allowable Subject Matter:

Claims 15-17 were objected to as being dependent upon a rejected base claim but would be indicated allowable if rewritten in independent form. Applicants thank the Examiner for the indication of allowable subject matter. However, Applicant respectfully submits that when the Examiner reconsiders the pending claims in view of the remarks herein, he will find that the remaining claims, claims 1-15 and 18-20, also contain allowable subject matter.

CONCLUSION


In sum, Applicant submits that the claims herein set forth a novel, non-obvious invention. Accordingly, Applicant submits that claims 1-20 as amended herein are in condition for allowance and respectfully petition for an early notice of allowance.

The previous Office Action, mailed November 4, 2004, set forth a three-month period for response. Accordingly, response is due on or before February 4, 2005. Thus, Applicant submits that this response is timely and no additional fees are required. However, in the event that additional fees are required to maintain the pendency of this application, the Commissioner is authorized to charge such fees to Deposit Account No. 50-2101.

Respectfully submitted,

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